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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/584,274	06/23/2006	Heinrich Haas	062587-5010	4612
9629 7590 11/24/2008 MORGAN LEWIS & BOCKIUS LLP 1111 PENNSYLVANIA AVENUE NW WASHINGTON, DC 20004				
EXAMINER				
DICKINSON, PAUL W				
ART UNIT		PAPER NUMBER		
1618				
MAIL DATE		DELIVERY MODE		
11/24/2008		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/584,274

Applicant(s)

HAAS ET AL.

Examiner

PAUL DICKINSON

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 8/6/2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/CDC)
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____
- Paper No(s)/Mail Date: _____

DETAILED ACTION**DETAILED ACTION**

Applicant's arguments, filed 8/6/2008, have been fully considered but they are not deemed to be fully persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objects are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Response to Arguments***Claim Rejections - 35 USC § 102 and 103***

The rejection of Claims 1, 3-7, 9-15 and 17-18 under 35 U.S.C. 102(b) as being anticipated by US 5556580 ('580) is maintained. The rejection of Claim 8 under 35 U.S.C. 103(a) as being unpatentable over US 5556580 ('580) is maintained.

Applicant argues that '580 does not disclose the claimed invention because '580 discloses extrusion of preformed liposomes. '580 discloses that "the liposomal material" is in an aqueous phase when extruded and contains liposomes that are formed prior to or during the extrusion process.

Applicant's arguments have been fully considered but are not found persuasive. The Examiner agrees that "the liposomal material" disclosed by '580 in some embodiments contains preformed liposomes prior to the extrusion steps. '580 teaches, however, that this material can be "in the form of liposomes or in a mixture of liposome constituents in nonliposomal form comprising any

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constituents that form or associate with liposomes... liposomal material will be understood to include lipids, aqueous media, and optionally organic solvents and bioactive agents" (see col 3, lines 54-59). Thus, in the broadest teaching of '580, the material to be extruded may include lipids (amphiphilic components) that are not preformed liposomes. The liposomal material disclosed by '580 is added to water after extrusion. Thus, '580 meets every limitation the instant claims.

New Grounds of Rejection

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 19-21 are rejected under 35 U.S.C. 102(b) as being anticipated by US 556580 ('580). '580 discloses a method for producing homogenous colloidal nanoparticles comprising (a) extruding a composition comprising a liposomal material by means of a compounder and (b) dispersing the extruded composition of step (a) in an aqueous medium (see abstract; col 3, line 13 to col 4, line 7). The liposomal material comprises lipids (an amphiphilic component) that are not formed into liposomes (see col 3, lines 54-59). The extrusion is performed at 100 psi (7 bar) and room temperature (approximately 22 °C) (see col 2, lines 65-67; Examples 3-4).

Claims 1 and 3-21 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5277914 ('914). '914 discloses a method of producing homogenous colloidal nanoparticles, comprising (a) extruding a composition comprising lipids (an amphiphilic component) and (b) dispersing the extruded composition of step (a) in an aqueous medium to form liposomes (see B. General Method). The extrusion is performed at 30 °C (col 7, lines 25-28).

Instant Claim 3 is directed to the FRET of the nanoparticles. Instant Claim 6 is directed to the polydispersity of the nanoparticles. Although '914 does not disclose all the characteristics and properties of the composition disclosed in the present claims, based on the substantially identical process using identical components, the Examiner has a reasonable basis to believe that the properties claimed in the present invention are inherent in the composition disclosed by '914. Because the PTO has no means to conduct analytical experiments, the burden of proof is shifted to the Applicant to prove that the properties are not inherent. "[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977)." MPEP § 2112, I.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **PAUL DICKINSON** whose telephone number is (571)270-3499. The examiner can normally be reached on Mon-Thurs 9:00am-6:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

Paul Dickinson
Examiner
AU 1618

November 20, 2008